K041446

JUL 01 2004

Summary Statement as defined in 21CFR 807.3

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Contact Ms. Benedicte Noury, Director of International Marketing

Name: Trade Name: NasalCEASE™
Common name: N/A
Classification name: calcium alginate

Substantially Equivalent to: ENTaxis (K985069)

Description of the device: NasalCEASE™ is comprised of interwoven strands of calcium alginate and is manufactured as a sheet (2x4x0.5 cm) weighing approximately 20mg that can be rolled along its long or short axis and inserted into the anterior nasal cavity.

Intended Use: NasalCEASE™ is intended to be inserted into the anterior nasal cavity to stop minor nosebleeds. It is intended to be marketed and sold as an Over-The-Counter device.

Technological Characteristics: NasalCEASE™ is comprised of interwoven strands of calcium alginate that can be rolled along its long or short axis and inserted into the anterior nasal cavity. Upon contact with blood or other physiological fluids in the nasal cavity it adsorbs those fluids and swells to apply a compressive force. ENTaxis acts in exactly the same way.

Non-clinical testing. A panel of physicians used the device and provided it to patients for use at home. Both physicians and patients were able to use the device correctly and effectively.

Summary: The NasalCEASE™ device described in this submission is substantially equivalent to the predicate device, is safe and effective, and sufficiently simplified and explained to be sold as an OTC product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 0 1 2004

LES Laboratories, S.A.
c/o Richard J. Freer, Ph.D.
Chairman and COO
601 Biotech Drive
Richmond, VA 23235

Re: K041446
Trade/Device Name: NasalCEASE™
Regulation Number: 21 CFR 874.4100
Regulation Name: Epistaxis balloon
Regulatory Class: Class I
Product Code: EMX
Dated: May 20, 2004
Received: June 1, 2004

Dear Mr. Freer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K041446

Device Name: NasalCEASE™

Indications for Use:

This device has the following intended use.

1. NasalCEASE™ is intended to be inserted into the anterior nasal cavity to stop minor nosebleeds. It is intended to be marketed and sold as an Over-The-Counter device.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K041446